HAMILTON MEDICAL

510(k) SUMMARY

MRIcompliant
Compatibility for up to 1 m.

NoCompAir
Independency with turbine.

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ESTABLISHMENT REGISTRATION NUMBER:	3001421318
PREPARATION DATE:	November 8th, 2013
TRADE NAME:	HAMILTON-MR1
CLASSIFICATION NAME:	CLASS II Ventilator, Continuous
REGULATION NUMBER:	21 CFR 868.5895
PRODUCT CODE:	CBK
PREDICATE DEVICE: (PRIMARY)	HAMILTON-C1 510(k) Number: K120574
PREDICATE DEVICE: (SECONDARY)	UNI-VENT Eagle II MR ventilator 510(k) Number: K111473 AESTIVA/5 MRI anesthesia system 510(k) Number: K050055

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K122438

DEVICE DESCRIPTION

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The HAMILTON-MR1 is an MR-Conditional ventilator which increases the availability of appropriate modes of therapy for ventilated hospital patients requiring MR imaging. It covers a full range of clinical requirements such as: invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and non-invasive Ventilation (NIV). It can be used at the 500 gauss line, in the presence of either 1.5T or 3T magnets.

In the MRI environment, where strong magnetic fields pose a danger for both the patient and the operator, safety is the highest priority. With the effectively shielded, MRI-compatible HAMILTON-MR1 ventilator, ventilation performance and MR image quality is guaranteed throughout the procedure. The integrated gaussmeter is programmed to alarm when the clinician is placing the HAMILTON-MR1 too close to the MRI magnet, which helps the clinician to properly position the HAMILTON-MR1 at the 50mT (500 gauss) line or less.

The HAMILTON-MR1 can be used in ICU special care areas, cardiac surgery recovery rooms, step-down or sub-acute care units, and when transporting patients to the MRI-department. In these cases, the HAMILTON-MR1 guarantees uncompromised continuous ventilation care from the ICU to the MRI and back with its 6-hour long batteries. Alternatively, the HAMILTON-MR1 can be used as an MRI-proprietary ventilator, waiting in the MRI department for the patient. In the MR environment -- when the clinician is unable to stay close to the patient for routine adjustments -- the ASV mode adapts to the patient's lung condition.

Positioning a medical device too close to the MRI can have fatal consequences and cause serious injury to the patient or clinician. In addition, significant financial losses can occur if an MRI shutdown is required. The HAMILTON-MR1's integrated gaussmeter continuously monitors the magnetic field and gives the clinician both an audible and a visual signal if the HAMILTON-MR1 is getting too close to the MRI magnet. For increased MRI safety and ease of use in the MR environment, the integrated gaussmeter continues monitoring -- even when the ventilator is not in use. Close proximity of the ventilator to the MRI machine is crucial. The HAMILTON-MR1 is a ventilator able to be used at a magnetic field strength of 500 gauss, without creating any MR image artifacts.

Both the HAMILTON-MR1's software and ventilation modes are identical to the HAMILTON-C1. One can operate the HAMILTON-MR1 with the touch-screen or with a single-turn wheel. Hard keys give direct access to the most important functions. The two devices are identical with the exception of modifications related to the MR environment (e.g. integrated gaussmeter, special alarm indicators, MR-specific labeling, the reduction in ferromagnetic materials, the removal of the options board, and increased safety measures for battery removal or replacement). Due to these modifications, the HAMILTON-MR1 is able to withstand the challenging conditions found in the MR environment. With the large alarm lamp, a clinician can immediately identify an alarming HAMILTON-MR1 ventilator because the alarm lamp is located at the top of the device, even if the clinician is a long distance away or when several different devices are operating simultaneously in the same room. The high-performance turbine can deliver up to 210 L/min flow, which is potentially helpful when using NIV modes of ventilation. The HAMILTON-MR1 includes a trolley made out of non-ferrous materials, which will not be attracted to the powerful electromagnetic forces emanating from the MRI's magnet. The trolley also has a "fail-safe" braking system (i.e., Dead man's brake).

INTENDED USE

The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

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Intended areas of use:

- In the MRI department
- In the intensive care ward or in the recovery room
- During transfer of ventilated patients within the hospital

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The HAMILTON-MR1 ventilator is classified as MR Conditional with the use of 1.5T and 3.0 Tesla static magnetic field scanners. The HAMILTON-MR1 ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

DISCUSSION OF THE NON-CLINICAL TESTS

	FDA Draft Reviewer Guidance for Ventilators (1995)
IEC 60601-1	General Requirements for Safety
IEC 60601-1-2	Electromagnetic Compatibility
IEC 60601-1-4	Programmable electrical medical systems
IEC 60601-1-8	Alarm Systems
IEC 60601-2-12	Critical Care Ventilators
IEC 62304	Software life-cycle processes
IEC 62366	Application of usability engineering to medical devices.
ISO 5356-1	Conical connectors: Part 1: Cones and sockets
ISO 5367	Breathing tubes intended for use with ventilators
AAMI/ANSI HE75	Human factors engineering. Design of medical devices
ISO 14971	Application of risk management to medical devices
ISO 21647	Basic safety and performance of respiratory gas monitors

Other internationally recognized standards which the HAMILTON-MR1 meets or exceeds:

ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment
ASTM F2052-06	Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment
ASTM F2119-07	Evaluation of MR Image Artifacts from Passive Implants
ASTM F2503-08	Marking medical devices for safety in the MR environment
IEC 62133	Battery safety standard. Non-spillable.
IEC 60601-1-6	Usability engineering process
ASTM F1100-90	Waveform performance and volume comparison testing
MIL-STD-461F	Immunity to conducted electromagnetic energy

COMPARISON WITH THE PRIMARY PREDICATE DEVICE

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PARAMETERS	HAMILTON-MR1 (Proposed device)	HAMILTON-C1 Predicate device: K120574	COMMENTS
Intended Use	The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics. Intended areas of use: • **In the MRI department** • In the intensive care ward or in the recovery room • During transfer of ventilated patients within the hospital **The HAMILTON-MR1 ventilator is classified as MR Conditional with the use of 1.5 T and 3.0 Tesla static magnetic field scanners.** The HAMILTON-MR1 ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics. Intended areas of use: • In the intensive care ward or in the recovery room • During transfer of ventilated patients within the hospital The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	Substantially equivalent. The differences in the intended use of the HAMILTON-MR1 are highlighted in **bold**. The only major difference between the HAMILTON-C1 and the HAMILTON-MR1 has to do with the additional protections which the HAMILTON-MR1 has, in order to withstand the high electromagnetic fields present near an MRI scanner. The HAMILTON-MR1 has passed rigorous testing to make sure that it will function properly in the MRI environment. Testing included: magnetic field interactions, heating, induced electrical fields, and artifacts.
Intended patient population	Patients include adults and pediatrics.	Patients include adults and pediatrics.	Equivalent
Maximum inspiratory flow	210 L/min	210 L/min	Equivalent
MRI-room compatible	Yes	No	Not equivalent
Temperature Range	5 to 40° C (operating), –20 to 60° C (storage)	5 to 40° C (operating), –20 to 60° C (storage)	Equivalent
Software version	Version 1.2.0	Version 1.1.2	Substantially equivalent
Number of batteries	2	1	Substantially equivalent
Weight	6.8 kg (15 lb), or 21 kg (46 lb) w/ trolley	4.9 kg (10.8 lb)	Substantially equivalent

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PARAMETERS	HAMILTON-MR1 (Proposed device)	HAMILTON-C1 Predicate device: K120574	COMMENTS
Operation environmental requirements	•5 to 40 °C (41 to 104 °F) •10 to 95%, non-condensing •1100 to 700 hPa	•5 to 40 °C (41 to 104 °F) •10 to 95%, non-condensing •1100 to 600 hPa	Substantially Equivalent
Input Power	AC: 100 to 240 V, 50/60 Hz	AC: 100 to 240 V, 50/60 Hz	Equivalent
Power Consumption	50 VA typical	50 VA typical	Equivalent
Battery	Two batteries, Li-ion, sealed, maintenance-free	One battery, Li-ion, sealed, maintenance-free	Substantially Equivalent
Battery operating time (typical)	5.5 hours	2 hours	Substantially Equivalent
Safety features	• Apnea backup ventilation • Automatic self-tests • Alarms (operator-adjustable / non-adjustable) • Alarm backup buzzer • External flow sensor failure mode • Safety mode in case of technical failures • Air inlet HEPA filter monitoring • Monitored fan • Event log	• Apnea backup ventilation • Automatic self-tests • Alarms (operator-adjustable / non-adjustable) • Alarm backup buzzer • External flow sensor failure mode • Safety mode in case of technical failures • Air inlet HEPA filter monitoring • Monitored fan • Event log	Equivalent
Emergency air intake	In case of a power supply, technical, or pneumatics failure the ambient valve allows spontaneous breathing.	In case of a power supply, technical, or pneumatics failure the ambient valve allows spontaneous breathing.	Equivalent
Maximum working pressure limit	60 cmH_20	60 cmH_20	Equivalent

The intended-use statement for the HAMILTON-MR1 ventilator is comparable to the primary predicate device. The only difference is that the HAMILTON-MR1 can also be used in the MR-environment. However, the technological characteristics (i.e., design and energy source) and the performance specifications of the HAMILTON-MR1 ventilator are equivalent to those of the HAMILTON-C1 predicate device. The HAMILTON-MR1 has not been tested for the inclusion of wireless connections into its USB-port, e.g. plug-in "dongles", as described in the FDA guidance on RF Wireless Technology in Medical Devices.

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MAGNETIC FIELD THRESHOLDS

Alarm/action	Magnetic field range	Accuracy
Green light - acceptable	≤ 50mT	± 10%
Yellow light - too close, alarm sounds	50 - 80mT	
Red light - too close, alarm sounds	> 80mT	
Red X light - technical fault, alarm sounds	--	

Note:
These values are based on a comparison with a commercially available, calibrated third-party gaussmeter. The HAMILTON-MR1's integrated gaussmeter's magnetic sensors are located at the center of the HAMILTON-MR1's enclosure; it consequently measures the gauss levels at the center of device. Furthermore, performance bench-testing has shown that gauss levels of 29mT in the center of the HAMILTON-MR1, correspond to ≤ 50mT on the outside of the HAMILTON-MR1's enclosure. Nevertheless, the HAMILTON-MR1 can function in accordance to its "essential performance criteria" at gauss levels of more than 100mT (1,000 gauss), although this is not recommended by HAMILTON MEDICAL. These performance tests were conducted using both the Philips Achieva 3.0T and 1.5T MRI scanners. For the dynamic field testing, HAMILTON MEDICAL used the compatibility protocols for third-party equipment validation recommended by Philips (e.g. MaxGrad, MaxB1+SAR, MaxGrad+RF).

In non-clinical testing, the device was found to be MRI safe to operate at (or less than) a fringe magnetic of 50mT. This testing was based on both ASTM F2213-06 (Magnetically Induced Torque) and ASTM F2052-06 (Magnetically Induced Displacement Force), which showed that the HAMILTON-MR1 with its brake activated, will only be pulled towards the MRI magnet at gauss levels of ≥ 445mT (4,450 gauss) with a magnetically induced force of 64.2 newtons. This test was conducted using a Philips Achieva 3.0 MRI scanner.

INTEGRATED GAUSSMETER

The HAMILTON-MR1 includes similar LED indicators to that of the AESTIVA/5 (K050055). The purpose for the three LED indicators on the integrated gaussmeter is to provide a visual representation of a range of gauss levels. For example, in the HAMILTON-MR1, the green LED shows that the integrated gaussmeter at the center of the ventilator is measuring gauss levels of 290 gauss (29mT) or less. This demonstrates that the HAMILTON-MR1 is considered to be located at an acceptably safe distance from the MRI scanner. The yellow LED represents a range of gauss levels from 300 gauss (30mT) to 690 gauss (69mT) at the center of the ventilator. At this range of gauss levels, the HAMILTON-MR1 will sound a warning alarm, as a signal to the operator that the ventilator is too close to the MRI scanner and should be moved back until the green LED is illuminated. The red LED represents a gauss level of at least 700 gauss (70mT) at the center of the ventilator. At that point, the red LED will continue flashing and the audible alarm will continue to be heard, even if the device were to be repositioned to safer distance from the MRI scanner. The HAMILTON-MR1 would then need to be serviced by a HAMILTON-MEDICAL trained specialist, in order to make sure that no permanent damage to the HAMILTON-MR1 has occurred.

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COMPARISON WITH OTHER MR-COMPATIBLE VENTILATORS

	Proposed device: HAMILTON-MR1	Maquet Servo-i (K063404)	CareFusion LTV 1200 MR (K083688)	GE Versamed iVent 201 MRI (K073694)	Impact Eagle II MR (K111473)
Maximum recommended magnetic induction	50mT (500 gauss)	~20mT (~200 gauss)	~10mT (~100 gauss)	~10mT (~100 gauss)	~20mT (~200 gauss)
Nearest distance to the MRI's bore opening	~1 m (3.25 ft)	~2.25 m (7.5 ft)	~2.75 m (9 ft)	~2.75 m (9 ft)	~2 m (6.5 ft)
Minimal Tidal Volume (V_T)	≥ 20 mL	≥ 100 mL	≥ 50 mL	≥ 100 mL	≥ 50 mL
Integrated Gaussmeter	Yes	No	No	No	No

CONCLUSION

The intended use of the HAMILTON-MR1 is substantially equivalent to the predicate devices. The HAMILTON-MR1's software has passed through verification/validation tests. A complete revision level history, hazard analysis, and a traceability analysis linking requirements to validation were done. The HAMILTON-MR1 includes a risk management report, system-level validation, verification testing according to the applicable standards, and testing in an MR environment. The conclusions drawn from the non-clinical tests demonstrate that the HAMILTON-MR1 is substantially equivalent to the legally marketed devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

Hamilton Medical AG
Mr. Ralph Aguila
Regulatory Affairs/Quality Engineer
Via Crusch 8
BONADUZ, GRISONS 7402
SWITZERLAND

Re: K122438
Trade/Device Name: HAMILTON-MR1
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, Continuous
Regulatory Class: II
Product Code: CBK
Dated: November 8, 2013
Received: November 12, 2013

Dear Mr. Aguila:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

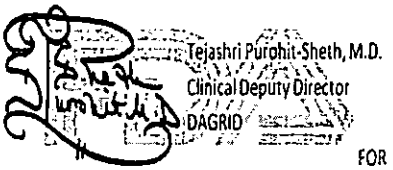
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Erin Keith, M.S.
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Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K122438

Device Name: HAMILTON-MR1

Indication for Use:

The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

Intended areas of use:

- In the MRI department
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Prescription Use ___X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.11.19 15:21:16 -05'00'